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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/589,034

10/10/2006

Michael Kratzer

HBC 255-KFM

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12/10/2009

ECKERT SEAMANS CHERIN & MELLOTT, LLC  
U.S. STEEL TOWER  
600 GRANT STREET  
PITTSBURGH, PA 15219-2788

EXAMINER

RAMDHANIE, BOBBY

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

12/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/589,034 | <b>Applicant(s)</b><br>KRATZER ET AL. |  |
|                              | <b>Examiner</b><br>BOBBY RAMDHANIE   | <b>Art Unit</b><br>1797               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6-14,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-11,14,16 and 17 is/are rejected.
- 7) ☒ Claim(s) 2,12 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Allowable Subject Matter***

1. Claims 2, 12, & 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
2. The following is a statement of reasons for the indication of allowable subject matter: Claim 2 recites that the device of Claim 1 further comprises a housing that has a cylinder and a piston disposed therein, and wherein the aperture is disposed in a bottom wall of the cylinder through which the blood from the reservoir can be passed during a corresponding movement of the piston; Claim 12 recites that the device of Claim 1 further comprises a small suction tube or a capillary, which extends into the reservoir, preceding the aperture, wherein the blood can be conveyed from the reservoir through the small suction tube or the capillary to the aperture; and Claim 13 recites that the device of Claim 12 further comprises the small suction tube or the capillary extends through the opening of the stirrer part.
3. The prior art of record does not suggest nor disclose the combination of these limitations with the device of Claim 1.

### ***Response to Arguments***

4. Applicant's arguments, see Remarks, filed 08/06/2009, with respect to Claims 1-4, 8, 10-12, & 14 as being anticipated or obvious by Boyd et al, and the combination

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Kratzer et al and Boyd et al, have been fully considered and are persuasive. The rejections of 102 & 103 under these references have been withdrawn.

5. Applicant's arguments filed 08/06/2009 with respect to the Bote Bote reference have been fully considered but they are not persuasive. The following reasons are why: Applicant argues the intended use and operation for the alleged invention (device), but this argument is unpersuasive because Applicants' claims are toward a device. The device of Bote Bote can function and operate in the same manner recited in Applicants' claims.

6. Applicants' allege that Bote Bote does not disclose continuous mixing during measurement. This argument is unpersuasive because Bote Bote discloses "due to rotation (movement in the longitudinal direction) of the rotor (2) both products are thoroughly mixed (continuous mixing during measurement), a biochemical process which, after a certain time, gives rise to a die clot." This section is interpreted as the device being continuously mixed during the measurement the time needed for the blood to coagulate.

### ***Response to Amendment***

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 6, 7, 14, & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bote Bote (WO03/087817; An English translation may be found as US7361306).

9. Applicants' claims are toward a device.

10. Regarding Claims 1, 3, 6, 7, 14, & 16, Bote Bote discloses the flow-through device for measuring the platelet function of primary hemostasis, the aggregation and/or the coagulation and/or the viscosity of the blood, with a reservoir, which is disposed in a housing and from which blood can be taken for the measurement and conveyed through an aperture, said device comprising a stirring device arranged in the reservoir and moved in such a manner, that a stirrer part of the stirring device thoroughly mixes the blood in the reservoir during the measurement and keeps it in motion (See Figure 1 Items 2, 7, & 8), wherein the stirrer part of the stirring device in the reservoir is disposed on a stirring rod (See Figure 1 Item 2 rotor is attached to a rod from Item 8), which extends in the longitudinal direction of the housing and can be moved in the longitudinal direction of the housing by a driving mechanism (See Figure 1 Item 2; rotor can be moved in the longitudinal direction), and wherein the stirring device, in the region of the blood supply of the reservoir, has no contact with stationary surfaces of the wall surroundings of the reservoir, so that squeezing of blood cells or other components of the blood can be prevented and substances, which are undesirably released and could lead to distortion of the results of the measurements, do not reach the blood (See Figure 1 Item 2 rotor does not touch the sides of the reservoir).

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11. Additional Disclosures Included: Claim 6: The stirrer part has the shape of a circular disk (See Figure 1 Item 2 rotor is in the shape of a circular disk); Claim 3: The housing has an opening region, through which the blood can be supplied to the reservoir of the housing (See Figure 1); Claim 7: The stirrer part extends essentially perpendicularly to the longitudinal direction of the housing (See Figure 1); Claim 14: Said device is constructed as a disposable part (See Figure 1, the device is disposable); and Claim 16: The stirrer part of the stirring device is mounted and can be moved in the reservoir without contacting the latter (See Figure 1; rotor ).

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 4, 8-11, & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bote Bote.

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1. Applicants' claims are toward a device.

14. Regarding Claims 4 & 10, Bote Bote discloses the device of Claims 3 & 9 respectively, wherein the opening region is in the shape of the housing, which is surrounded by the socket-shaped, outwardly inclined side wall region of the housing (See Figure 1). Bote Bote does not disclose that the opening region is in the shape of a curved projection of the housing. Bote Bote does however disclose that the opening is in the shape of the housing (See Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shape of the opening to be in the shape of a curved projection to obtain faster mixing of the blood and coagulation activator, since it has been held that the provision of adjustability, where needed, involves routine skill in the art. In re Stevens, *101 USPQ 284* (CCPA 1954).

15. Additional Disclosures Included: Claim 10: The curved projection has a rectangular cross section (See Figure 1).

16. Regarding Claims 8, 9, 11, & 17, Bote Bote discloses the device of claim 1, except wherein the stirring rod, at its side averted from the stirrer part, has a step part, which protrudes through a slot-shaped opening, which extends in the longitudinal direction of the housing, radially to the outside and can be moved by the driving mechanism, so that the stirrer part can be moved back and forth in the longitudinal direction of the housing in the interior of the reservoir.

17. Bote Bote does however disclose that after a certain amount of time (after the reactants are mixed thoroughly, a clot forms which causes a increase in mechanical

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friction between the rotor and the cup (See Column 2 lines 42-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stirring rod at its side averted from the stirrer part, to have a step part, which protrudes through a slot-shaped opening, which extends in the longitudinal direction of the housing, radially to the outside and can be moved by the driving mechanism, so that the stirrer part can be moved back and forth in the longitudinal direction of the housing in the interior of the reservoir in order to break the blood that has clotted from between the surface of the rotor from the cup at the end of the test.

18. Additional Disclosures Included: Claim 9: The housing has a curved projection, which extends in the longitudinal direction of the housing and opens up into the reservoir, wherein the stirring rod is disposed in the curved projection in the region of the reservoir and wherein a slot-shaped opening is disposed in the curved projection and above the reservoir (See Rejections to Claim 4 above); Claim 11: The curved projection is disposed opposite to a further projection formed in an opening region, through which blood can be supplied to the reservoir of the housing (See Figure 1 Item 3); Claim 17: The rod stirring the stirring device is mounted and can be moved in the curved projection without contacting it (See Figure 1 & Rejections above to Claim 1).

### ***Telephonic Inquiries***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

24. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the

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Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797